

Multiplate 5.0: 510(k) Summary

Version: 1.0 / Date: 26.07.2012

Released by: Verum Diagnostica GmbH

**multiplate®**

Device:	Multiplate Analyzer 5.0
Prepared on:	November 29, 2010
Submitted by:	Verum Diagnostica GmbH, Reichenbachstrasse 27, 80469 Munich, Germany
Contact person:	Dr. Maximilian Zucker, +49 89 12 55 56-0
Device Names:	<ul style="list-style-type: none"> - Trade name: Multiplate 5.0 - Common name: Whole Blood Analyzer - Classification name: Automated Platelet Aggregation System

The Multiplate 5.0 has been found to be substantially equivalent to the previously cleared Chrono-log Model 700 Whole Blood Lumi-Aggregometer (K050265).

1. Device Description

The Multiplate® 5.0 measures platelet function in whole blood samples using electrical impedance. The Multiplate technology employs multiple electrodes in a disposable test cell. Four electrodes form two independent sensor units allowing for two measurements on the same sample. Five independent channels of the instrument allow for testing of multiple reagents or samples simultaneously.

The instrument provides a five channel aggregometer and an integrated computer system with associated software and is connected to a computer screen, keyboard, mouse, and an electronic pipette. The software is used for data collection and is not used for diagnosis or treatment.

Currently, two test reagents (ADP and Arachidonic acid) are available that activate platelets through specific platelet membrane receptor/signal transduction pathways in order to measure platelet function or alterations in function.

2. Intended Use

The Multiplate 5.0 aggregometer is intended for in vitro use to measure platelet aggregation in response to Arachidonic acid or ADP in citrated whole blood samples for the qualitative assessment of platelet function.

The ADPtest reagent is a lyophilized preparation of adenosine-5-diphosphate for in vitro diagnostic use to measure platelet aggregation for the qualitative assessment of platelet function. For professional laboratory use only.

The ASPItest reagent is a lyophilized preparation of arachidonic acid (AA) for in vitro diagnostic use to measure platelet aggregation for the qualitative assessment of platelet function. For professional laboratory use only.

3. Technical Description

The Multiplate uses the same scientific principles of detection as the predicate Chrono-log Model 700 with the exception that it does not include the capability of platelet function measurement based on luminescence or turbidimetric light transmission measurement.

Both devices employ the same principle of measurement: electrical impedance, first cited in 1980 by Cardinal and Flower, (J Pharmacol Methods.1980;3:135-158). An electrical current passes through individual sets of electrodes. When the electrodes come into contact with a whole blood sample platelets bind to and cover the electrodes in a small monolayer. As the platelets become activated after exposure to a specific platelet agonist, the platelets strongly adhere to the electrodes and begin to aggregate. An increase in the number of platelets adhering to the electrodes increases the resistance (impedance) between the pair of electrodes.

Potential improvements of the Multiplate system are the introduction of dual sensor technology that records two measurements in each test cell based on two individual pairs of electrodes. The mean value is then reported. The final measurement is reported in Units (U) which represents the area under the curve that is generated by graphing the change in resistance.

4. Performance

Multi-center studies were run to compare the performance of the Multiplate 5.0 to the predicate device. Samples from 171 patients suspected of decreased platelet function were drawn and measured in duplicate.

The positive and negative percent agreements of the Multiplate to the Chrono-log were calculated. The results were considered positive if the test value was below the reference range for the specific device. The results were considered negative if they fell within the reference range for the specific device. Using this data, the positive percent agreements (PPA) and negative percent agreements (NPA) were calculated.

	Arachidonic acid		ADP	
	PPA	NPA	PPA	NPA
Agreement	100%	65%	93%	54%
95% Confidence Interval	[96%, 100%]	[54%, 75%]	[81%, 97%]	[45%, 62%]

Sensitivity and Specificity were analysed by considering samples from 91 patients suspected of decreased platelet function which were drawn and measured in duplicate. Clinical sensitivity and specificity were calculated against Platelet Function Status. Platelet Function Status of each sample was based upon a physician panel's review of each patient's clinical history.

	Sensitivity	Specificity
ASPItest	93%	67%
95% CI	[85%, 97%]	[44%, 84%]
ADPtest	59%	80%
95% CI	[46%, 70%]	[63%, 90%]

5. Conclusion

The data and information provided in this submission demonstrate substantial equivalence and support clearance of the 510(k) premarket notification for the Multiplate 5.0 and associated reagents.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG - 7 2012

Verum Diagnostica GmbH
c/o Maximilian Zucker, Ph.D.
Reichenbachstrasse 27
80469 Munich
Germany

Re: k103555

Trade/Device Name: Verum Multiplate 5.0
Regulation Number: 21 CFR 864.5700
Regulation Name: Automated Platelet Aggregation System
Regulatory Class: Class II
Product Code: JOZ
Dated: June 19, 2012
Received: June 22, 2012

Dear Dr. Zucker:

This letter corrects our substantially equivalent letter of July 27, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

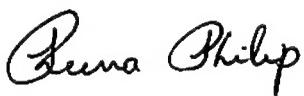
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K103555**

Device Name: **Multiplate 5.0 (Indications for Use of the ADPtest)**

Indications For Use:

The ADPtest reagent is a lyophilized preparation of adenosine-5-diphosphate for in vitro diagnostic use to measure platelet aggregation for the qualitative assessment of platelet function. For professional laboratory use only.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)


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Device Evaluation and Safety

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Indications for Use

510(k) Number (if known): K103555

Device Name: Multiplate 5.0 (Indications for Use of the ASPItest)

Indications For Use:

The ASPItest reagent is a lyophilized preparation of arachidonic acid (AA) for in vitro diagnostic use to measure platelet aggregation for the qualitative assessment of platelet function. For professional laboratory use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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NEEDED)

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Reena Philip
Division Sign-Off

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Device Evaluation and Safety

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Indications for Use

510(k) Number (if known): K103555

Device Name: Multiplate 5.0 (Indications for Use of the Liquid Control Set)

Indications For Use:

For use as an assayed quality control verification of the resistance measure of impedance aggregometry.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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